

## REMARKS

Upon amendment, Claims 1-4, 6, 9-12, 14, 16-17, 19 and 21-22 are pending in this application. Claim 16 stands withdrawn. Claims 5, 7-8, 13, 15, 18, 20, and 23-29 have been canceled without prejudice. Claims 1-4, 6, 9-12, 14, 17, 19 and 21 have been amended to encompass the elected subject matter and to more clearly define the claimed subject matter. No new matter has been added by the amendments. Support for the amendments is found throughout the application and claims as originally filed.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is in condition for allowance.

### Objections to the Title and Abstract

The Title has been objected to as “not descriptive.” Applicants have amended the title to be indicative of the invention to which the claims are directed.

The abstract has been objected to because “in chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its

use.” Applicants respectfully feel that the abstract as originally filed satisfies the requirements for an abstract. That is, it is believed that the abstract enabled “the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure.” (37 C.F.R. 1.72(b)). Nevertheless, Applicants have amended the abstract to include general formula (I-A) as well as to follow more closely with the language in the claims.

### **Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 1-12, 14 and 17 are rejected under 35 U.S.C. 112, First Paragraph, as failing to comply with the enablement requirement. In particular, the Office Action alleges that “the specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make the compounds and compositions of the invention commensurate in scope with these claims” Applicants respectfully disagree.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* ("MPEP") § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement ... unless there is a reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support

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It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

*Id.* (emphases added).

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. (*See U.S. v. Telectronics, Inc.*, at 785).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

For example, the specification teaches that the compounds of the present invention can be synthesized by using the methods described on pages 16-18 of the specification, provides solvents, acids and bases for the various reaction steps on pages 18- 20 and states that "the [intermediate] compounds of the general formulas (II), (III), (I), (V) and (VI) are known *per se*,

or they can be prepared by customary methods.” (Page 20, lines 27-28). Similarly, the specification discloses a schematic synthesis for the compounds of the invention. Finally, the specification discloses synthetic methods in the specific examples. As such, these teachings would clearly enable one of ordinary skill in the art to readily make and use any of the compounds encompassed by the present claims without undue experimentation, as required by 35 U.S.C. § 112, first paragraph.

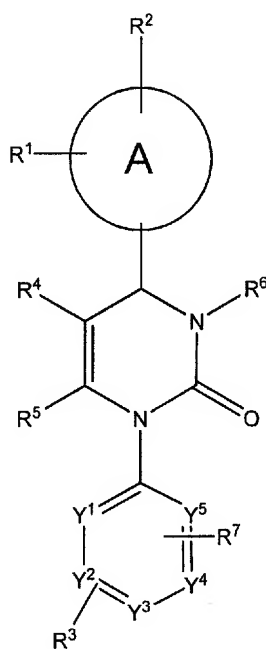
Applicants respectfully submit that: (1) the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention; (2) the Examiner did not provide any factual or legal basis to doubt that the claims are enabled; and (3) to the extent any experimentation is necessary, such experimentation is not undue. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn

## Double-Patenting Rejections

Claims 1-12, 14 and 17 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-12 and 14 of U.S. Patent Publication Application No. 2008/0021053 (“the ‘053 publication”).

The Examiner states that the ‘053 publication teaches a compound of the general formula

(I)



which varies “in the 2 position of the pyrimidine, where the published reference teaches a 2-one derivative, while the current application teaches a 2-thione derivative.” The Examiner relies on the decision of *Graver Tank & Mfg. Co. v The Linde Air Products Co.* (USSC 1950) 339 U.S. 695, 85 USPQ 328, to argue equivalency of the compound or composition. That is, “both elements [oxygen and sulfur] fall within the same family in the periodic table...contain the same valence number, similar chemical properties, and numerous chemical literature has

suggested the attempted use of a thiol over an alcohol or a thiourea in place of a urea and vice versa.” Applicants respectfully note that the Examiner has not provided any of the references alluded to by this statement.

Applicants respectfully disagree with the Examiner that such a modification would not alter or affect the claimed compounds in any way. To that end, Applicants respectfully draw the Examiner’s attention to Gomez *et al.*, Urea vs. thiourea in anion recognition, *Org. Biomol. Chem.*, 2005, 3, 1495 – 1500 (Exhibit A), which concludes that, “the more acidic *thiourea* containing receptor deprotonates in the presence [of] all the investigated anions except chloride, whereas the less acidic *urea* containing receptor undergoes deprotonation only in the presence of fluoride” and that while “the choice of the receptor should be directed towards the most acidic H-bond donors....a receptor which is too acidic, like thiourea, leads to the formation of complexes which are intrinsically stable but are unstable with respect to HX release and deprotonation.” As such, the more acidic thiourea moiety can react very differently than a similar less-acidic urea compound. This would be true both in terms of the synthesis of the compounds (i.e., using a urea based starting material in the synthesis in place of the thiourea starting material), as well as in the eventual use of the compounds *in vivo*.

As such, one of ordinary skill in the art would not have necessarily been motivated to synthesize the same compounds with a C=S in place of C=O without potentially arriving at a completely different final product, let alone a final product with similar beneficial properties when used in the methods of the invention. As such, it is believed that the obviousness-type double patenting rejection is improper and should be withdrawn.

Nevertheless, as it remains unknown what subject matter claimed and disclosed in the present application will be deemed allowable; any statement regarding these rejections made on Applicants' part is premature. Therefore, Applicants respectfully traverse these rejections, and request that these rejections either be withdrawn as stated above, or be held in abeyance until subject matter is deemed allowable in this application.

### CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

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Respectfully Submitted,

By: /Nicholas J. DiCeglie, Jr./  
Nicholas J. DiCeglie, Jr.  
Registration No. 51,615  
Attorney for Applicant  
EDWARDS ANGELL PALMER & DODGE LLP  
P.O. Box 55874  
Boston, MA 02205  
Telephone: 212-308-4411  
Facsimile: 212-308-4844